Global Fund Quality Assurance Policy for Pharmaceutical Products

Expert Review Panel

Indicative Terms of Reference

General Principles

Part 1: Background

1. At its 18th Meeting in November 2008, the Global Fund Board approved a revised Quality Assurance Policy for Pharmaceutical Products ("QA Policy"), as set out in the attached Board Decision (GF/B18/DP11). The QA Policy shall come into effect on 1 July 2009 and shall replace the Global Fund's previous policy for the quality assurance of pharmaceutical products.

2. The QA Policy provides that Global Fund grant funds may only be used to procure antiretrovirals, anti-tuberculosis and anti-malarial finished pharmaceutical products (FPPs) that meet the following standards:

   (i) Prequalified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA)[1]; or

   (ii) Recommended for use by an Expert Review Panel (ERP).[2]

3. The Board has authorized the Secretariat to request the World Health Organization (WHO) to host the ERP and to conclude the necessary arrangements with WHO.

4. This document sets out an indicative the terms of reference for the ERP and will be subject to final approval following a review by the PC at its 11th Meeting in March/April 2009.

Part 2: Purpose of the ERP

1. As defined in the QA Policy, the ERP will be an independent technical body hosted by WHO that is composed of external technical experts.

2. The purpose of the ERP is to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized. The ERP will make recommendations to the Global Fund on whether to allow grant funds to be used to procure such FPPs.

[1] A Stringent Drug Regulatory Authority means a regulatory authority which is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

[2] Section 7 of the QA Policy

Part 3: Division of functions between Global Fund Secretariat and the ERP

1. The Global Fund Secretariat will be responsible for:

   (i) inviting manufacturers of selected medicines to submit an Expression of Interest (EoI) to have FPPs reviewed by the ERP;

   (ii) publishing guidelines on the application process for ERP review;

   (iii) managing the receipt of product dossiers sent by manufacturers according to the EoI guidelines;

   (iv) providing complete product dossiers to the ERP Coordinator at WHO for review;

   (v) notifying manufacturers of the outcome of the ERP's review of their respective FPP dossiers; and

   (vi) maintaining on its website an up-to-date list of all FPPs that have been recommended for use by the ERP.

2. The ERP hosted by WHO will be responsible for:

   (i) establishing rules of procedure and criteria for ERP reviews;

   (ii) reviewing product dossiers with a particular focus on the technical information described in Part 6 below; and

   (ii) delivering to the Global Fund a report detailing the findings of each such review, including recommendations on whether to allow grant funds to be used to procure the FPP in question, within the timeline agreed with the Global Fund.

Part 4: ERP Membership

1. WHO will recruit an ERP Coordinator to be responsible for managing the selection and recruitment of ERP members in consultation with the WHO Prequalification Programme.
2. The ERP shall consist of a pool of at least 15 senior experts who may be called upon, from time to time, to participate in the review of product dossiers. Out of that pool, a maximum of seven experts will be selected by the ERP Coordinator to conduct a specific dossier review.
3. ERP membership shall be representative of a wide range of expertise in the pharmaceutical and medical fields. Each ERP Member shall have extensive professional experience in at least one of the following technical areas: (i) quality assurance of pharmaceuticals; (ii) quality control of pharmaceuticals; (iii) pharmaceutical regulatory affairs; (iv) disease control; (v) pharmaceutical manufacturing; and/or (vi) clinical and/or biopharmaceutics/pharmacokinetics.
4. ERP Members shall serve in their personal capacities only (that is, they shall not represent their employers or another organizations when serving as ERP members). The names and curricula vitae of ERP members shall be made available to the public.
5. ERP members are covered by the requirements of the Global Fund's Policy on Ethics and Conflict of Interest for Global Fund Institutions ("Ethics Policy"). Accordingly, each member shall be required to complete and submit declaration of interest forms to the Global Fund's Ethics Official in accordance with the requirements set out in the Ethics Policy.
6. ERP members are also required to sign a confidentiality statement prepared in accordance with the ERP's internal guidelines.[3]

[3] Such guidelines shall be developed by the ERP.

Part 5: Scope of work of the ERP

1. As requested by the Global Fund, the ERP shall assess the quality of FPPs that meet the eligibility criteria set out in section 13 of the Quality Assurance Policy for Pharmaceutical Products issued by the Global Fund from time to time.
2. For each such assessment, the ERP shall review selected parts of the product dossier that have been sent to the ERP Coordinator from the Global Fund. The ERP assessment shall focus on the technical areas specified in Part 6 below.
3. The ERP shall prepare and submit a report to the Global Fund, which outlines the key findings of its review and provides a recommendation on whether the Global Fund should allow the FPP to be procured with grant funds.
4. The ERP review process should be conducted in accordance with in close collaboration with the WHO Prequalification and WHO disease programmes.

Part 6: Technical Areas of ERP review

1. The ERP will review a product dossier, focusing on the following technical areas:

   (i) product registration information;

   (ii) regulatory (licensing) status of the FPP and details about the manufacturing facility;

   (iii) finished product specifications and information regarding compliance with international pharmacopoeia standards, if available;

   (iv) stability testing data (both accelerated and real time studies in Zone IV) as per ICH and/or WHO Guidelines;

   (v) product labelling information;

   (vi) active pharmaceutical ingredient (API) characteristics and certification; and

   (vii) safety and efficacy data or human bioequivalence data.

Part 7: Validity of the ERP recommendations

As specified in the QA Policy, if the ERP recommends the use of an FPP, the ERP's recommendation shall be valid for a period of no more than 12 months ("ERP Recommendation Period"), or until the FPP is WHO-prequalified or SRA-authorized[4], whichever is the earlier. However, the Global Fund may, in its sole discretion, request the ERP to consider extending the ERP recommendation period for up to an additional 12 months if the FPP is not yet WHO-prequalified or SRA-authorized within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

Part 8: Transparency

Guidelines on the application process for ERP reviews will be made publicly available on the Global Fund website. All FPPs recommended for use by the ERP will also be made publicly available.

[4] Or approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval.

Part 9: Logistics

ERP members may receive an honorarium for their services, as approved by the Global Fund, in addition to travel expenses and perdiems.

The ERP is supported by the Secretariat to facilitate its activities, in particular with regards to the arrangements for the ERP sessions as well as provision of the relevant documentation for review.

Part 10: Evaluation of the ERP

No later than 18 months after the establishment of the ERP, the Global Fund will evaluate the performance of the ERP against the indicators that will be set forth in the contract between the Global Fund and the WHO.